UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/251,133	02/16/99	SHAH G	70009590-001

HM22/1002

JOSEPH A. MAHONEY
MAYER, BROWN & PLATT
P.O. BOX 2828
CHICAGO IL 60690-2828

EXAMINER	
HOLLERAN, A	
ART UNIT	PAPER NUMBER
1642	17

DATE MAILED: 10/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/251,133	Applicant(s) SHAH, GIRISH V.	
	Examiner Anne Holleran	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) *1 and 4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3 and 5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group II, claims 2, 3 and 5, in Paper No. 16 (filed July 26, 2001) is acknowledged. Applicant's further election of SEQ ID NO: 6, within group II is also acknowledged. Applicant's further election of species of antibody (for compostions of claims 3 and 5) is also acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-5 are pending.

Claims 1 and 4, drawn to non-elected inventions, are withdrawn from consideration.

SEQ ID NOS: 1, 7, 8, 9, 10, 11 and 12, drawn to separate and distinct, and non-elected sequences, are withdrawn from consideration. Applicant is required to amend claims 2, 3 and 5 to read only on SEQ ID NO: 6.

Claims 2, 3 and 5, to the extent that they read on inventions comprising SEQ ID NO: 6 are examined on the merits.

Informalities

2. Claim 2 is objected to for improperly reciting sequence identifiers. The proper form is SEQ ID NO:X. Correction is required.

Claim Rejections - 35 USC § 112

3. Claims 2, 3, and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite for reciting "substantial homology". The scope of the claims cannot be determined because the specification fails to provide any definition for "substantial homology".

Claim 2 is also indefinite because it depends from a claim that is withdrawn from examination.

4. Claims 2, 3 and 5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 2 is drawn to a peptide that is encoded by a cDNA that has substantial homology with a cDNA sequence of a cDNA sequence selected from the group of SEQ ID NO: 2, SEQ IDNO: 3, SEQ ID NO: 4 and SEQ ID NO: 5, and has substantial homology to a peptide comprising the sequence of SEQ ID NO: 6. A review of the specification shows that a peptide comprising the amino acid sequence of SEQ ID NO: 6 may be derived from the polynucleotide sequence of SEQ ID NO: 3. Apparently, SEQ ID NO: 3 has multiple reading frames, and the peptide consisting of the amino acid sequence of SEQ ID NO: 6 is one of three possible amino

acid sequences. Thus, the disclosure of SEQ ID NO: 6 is the disclosure of a putative amino acid sequence of a peptide that may not actually be expressed.

Because of the substantial homology language, claim 2, and therefore, dependent claims 3 and 5, are genus claims, that encompass many peptides having varied sequences. Because the phrase "substantial homology" is indefinite, the specification fails to provide any structural information that would lead one of skill in the art to understand what is the common structural features of the claimed genus of peptides.

The specification discloses that a peptide having the sequence of SEQ ID NO: 1 has been isolated from cells subscloned with a cDNA sequence having the nucleotide sequence of SEQ ID NO: 2. This peptide is apparently referred to as NEM in the specification. It is not clear from the specification the extent of the structural relationship between SEQ ID NO: 1 and SEQ ID NO: 6. A sequence search of SEQ ID NO: 6 against the pending U.S. application files does not show that SEQ ID NO: 6 has any relationship with SEQ ID NO: 1 because the two sequences do not appear to overlap.

Thus, the disclosure of NEM (which may be a protein having the sequence of SEQ ID NO: 1) and the disclosure of SEQ ID NO: 6 are not representative of a family of peptides that have structural similarities. Thus, it does not appear that the specification describes a genus of peptides having "substantial homology" with SEQ ID NO: 6. Therefore, one of skill in the art would not understand that applicant was in possession of the claimed inventions.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claim 2 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 2 is directed to a peptide that is neither isolated nor purified. Thus, the peptide of claim 2 appears to encompass a product of nature. oc

6. Claims 2, 3 and 5 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, substantial and specific asserted utility, or a well-established utility. ~o

Claim 2 is examined to the extent that it reads on a peptide having substantial homology to an amino acid sequence of SEQ ID NO: 6. SEQ ID NO: 6 appears to be a putative amino acid sequence derived from a putative reading frame of the cDNA sequence of SEQ ID NO: 3, which is itself an alternate reading frame of SEQ ID NO: 2. Thus, the peptide of SEQ ID NO: 2 does not appear to be completely characterized in structure or function. The closest alignments found in a database search of the sequence of SEQ ID NO: 6 are amino acid sequences of plant proteins that are much larger than the amino acid sequence of SEQ ID NO: 6 (alignments enclosed). One alignment is that of a putative rat testis protein. The percentage of match between all of the alignments varies from 34.8 percent (rat protein) to 37.6 percent (a plant protein). Thus, a search of the prior art does not reveal structural evidence to support a claim to any function for a peptide having a sequence of SEQ ID NO: 6 or having substantial homology to an amino acid sequence of SEQ ID NO: 6.

The specification teaches attributes of a protein referred to as "NEM" and asserts that NEM may be a prostate growth factor or marker. However, the specification fails to teach the exact structural relationship between "NEM" and a peptide having the amino acid sequence of SEQ ID NO: 6, or having structural homology to a sequence of SEQ ID NO: 6. Thus, the teachings of the specification cannot be used to support a claim for any type of utility for peptides having an amino acid sequence of SEQ ID NO: 6, or having substantial homology to SEQ ID NO: 6. Therefore, the specification appears to present nothing more than an invitation to research to discover a credible, substantial and specific utility for a peptide having the amino acid sequence of SEQ ID NO: 6, or having substantial homology to a sequence of SEQ ID NO: 6.

7. Claims 2, 3, and 5 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible, substantial and specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Factors to be considered in determining whether undue experimentation would be required to practice the claimed invention, or the full scope of the claimed inventions are: 1) quantity of experimentation necessary; 2) the amount of direction or guidance presented in the specification; 3) the presence or absence of working examples; 4) the nature of the invention; 5) the state of the prior art; 6) the relative skill of those in the art; 7) the predictability or unpredictability of the art; and 8) the breadth of the claims. See Ex parte Forman, 230 USPQ 546, BPAI, 1986.

The specification provides no guidance for the use of a peptide that consists or comprises an amino acid sequence of SEQ ID NO: 6, because all of the experimental examples appear to apply to a protein having the amino acid sequence of SEQ ID NO: 1, which is a sequence that does not appear to bear any structural similarity with the amino acid sequence of SEQ ID NO: 6. Furthermore, the full scope of claims 2, 3 and 5 include peptides, or compositions comprising the peptide of claim 2, that have substantial homology to SEQ ID NO: 6.

The prior art teaches that the art of protein chemistry is highly unpredictable, and that even seemingly inconsequential changes in the primary sequence of a polypeptide can result in large changes in the biological activity of the polypetide (see Lazar, E. et al, Molecular and Cellular Biology, 8(3): 1247-1252, 1988; and Burgess, W.H. et al., J. Cell Biology, 111: 2129-2138, 1990). Since the biological activity of a protein largely determines many of the possible utilities for a protein, it would appear that the specification fails to provide adequate support for the breadth of claims 2, 3 and 5, because these claims read on products defined by "substantial homology" to a given sequence. Because the working examples are apparently directed to a protein with a sequence that has no common structural feature with a peptide having the amino acid sequence of SEQ ID NO: 6, it would appear that the information provided by the working examples fails to provide support for even the one embodiment of a peptide having an amino acid sequence of SEQ ID NO: 6.

Because the specification fails to provide guidance for the use of peptide that consists of or comprises an amino acid sequence of SEQ ID NO: 6, the quantity of experimentation necessary to determine a use for a peptide of SEQ ID NO: 6 would be large. Furthermore, such experimentation would involve experimentation on the peptide itself to determine whether it is a

peptide that is actually expressed, to determine what biological activity is might possess or determine if it has any association with a disease state. Therefore, the guidance provided by the specification appears to be nothing more than an invitation to do further research on the product being claimed.

Because the specification provides inadequate guidance, the prior art teaches the unpredictability of protein chemistry and its relationship to protein biological activity and because of the nature and extent of the experimentation required, the specification is not enabling for how to use peptides having the sequence of SEQ ID NO: 6, nor is it enabling for the full breadth of how to use peptides that merely have "substantial homology" to a peptide having an amino acid sequence of SEQ ID NO: 6.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

ALH

Anne L. Holleran
Patent Examiner
October 1, 2001

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600